

Application No. 09/830,708  
Filed: April 30, 2001  
TC Art Unit: 1651  
Confirmation No.: 3616

#### REMARKS

Claims 1-6 and 8-22 are pending in the present application. Claims 15-22 are cancelled herein, without prejudice, for non-elected claims. Claim 1 is amended herein. Accordingly, claims 1-6 and 8-14 will be pending upon entry of the instant amendments.

Support for the amended claims can be found throughout the specification and encompassed by the scope of the claims as originally filed. In particular, support for the amendment to claim 1 can be found, at least, for example, starting on the bottom paragraph of page 22 to the top of page 23 or page 23, first line in the 3<sup>rd</sup> paragraph. No new matter has been added.

Any amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and were done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

#### Claim Rejections - 35 U.S.C. §102

The rejection of claims 1 and 8 is maintained over Lee et al. and newly rejected over Shamsuddin and Krepinsky (U.S. Patent 6,187,591). The Examiner takes the position that with respect to Lee et al., "the present claims are not based on absolute color, they are based on "spectrophotometrically measuring hue angle or chroma" which reads on most types of standard spectrophotometric determinations including wavelength change or reflectance. Shamsuddin spectrophotometrically reads color changes due to chromogenic reactions. Krepinsky (6,187,591) teaches in the abstract, determining a coloration produced at about 560-590 nm by the sample."

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Applicant respectfully traverses the foregoing rejection.

In the presently amended claims, the invention is directed to a process for analyzing a specimen of biological material in a biochemical or immunological test for an analyte comprising the steps of: subjecting said specimen to treatment that develops a color correlating to the amount of analyte in the specimen; spectrophotometrically measuring hue angle with or without chroma of the developed color to obtain a value; and electronically processing the value obtained from the measurement of the hue angle with or without chroma to determine the presence or concentration of the analyte in the specimen (Claim 1). The specimen is deposited on a white substrate that is non-cellulosic where it is further processed for color by an enzymatic reaction or Schiff's reaction (Claim 8). The present application applies hue angle with or without chroma in a novel way where significant advances are made in the accurate interpretation of color-based biological and biochemical reactions.

Lee et al. is directed to a pressure-assisted apparatus and method of determining, in a liquid sample, the presence of an analyte. Lee et al. fails to anticipate each and every element of the claimed invention. In the apparatus of Lee et al., the use of a superatmospheric pressure is emphasized to create a pressure differential across the filter means to provide substantially better results than are obtained with the use of a vacuum to create the pressure differential. Lee et al. makes a tangent reference to color measurement such that the spectrophotometric measurement of a developed color is distinguishable from the present invention.

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The present claims electronically measures hue angle with or without chroma to determine the presence or concentration of the analyte in the specimen. Lee et al. interprets a positive test by using a color chart (page 16, second full paragraph). Unlike the present invention, Lee et al. interprets its data subjectively. The present invention uniquely provides results that are based on objective parameters. As explained in the Declaration of Michael Evelegh, the present application involves an electronic measurement of color with a reflectance spectrometer and color measuring software to calculate the hue angle with or without chroma obtained by a biological sample. Lee et al. cannot anticipate a spectrometer measurement of the hue angle with or without chroma based on the disclosure that, "[t]he total color difference data obtained is a composite unit and depends upon the a) dark/light difference; b) red/green difference; c) yellow/blue difference; and d) chromaticity difference (chromaticity and hue)." Lee et al. incorrectly applies chromaticity and hue when a single positive value is determined for DE. As stated in Dr. Evelegh's declaration in paragraph 11, DE "is a single number indicating the total or collective color difference between standard and sample. It describes merely a magnitude of a color difference, but does not indicate in any way in what direction those differences may be." In the present invention, an electronic value is determined for hue angle (a vector) in the entire visible spectrum, generally between the wavelength range of about 400-700 nm, with or without chroma, which is the amount of identifiable hue present in each color. The context in which chromaticity and hue is described in Lee et al. cannot anticipate each and every element of the claimed invention.

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Additionally, neither Shamsuddin nor Krepinsky anticipate the claimed invention. As Dr. Eveleigh's declaration (paragraph 12) indicates, Shamsuddin and Krepinsky simply measure wavelength at a single point or narrow range (e.g., 560-590 nm). The cited references fail to anticipate spectrophotometrically measuring hue angle with or without chroma and electronically processing the value obtained from the measurement of the hue angle with or without chroma to determine the presence or concentration of the analyte. Applicant respectfully requests reconsideration and withdrawal of the foregoing rejection.

Claim Rejections - 35 U.S.C. §103

Claims 1-6, 8, 10 and 11 are rejected under 35 U.S.C. §103(a) as being obvious over the combination of each of Shamsuddin (U.S. Patents 4,857,457; 5,162,202 and 5,348,860) in view of Lee et al. (WO/90/00251). Claims 1-6 and 8-11 are rejected under 35 U.S.C. §103(a) as being obvious over the combination of Krepinsky (U.S. Patent 5,416,025) in view of Lee et al. Additionally, claims 1-6 and 8-14 are also rejected under 35 U.S.C. §103(a) as being obvious over the combination of Krepinsky (U.S. Patent 6,187,591) in view of Lee et al. And, finally, claim 12 is rejected under 35 U.S.C. §103(a) as being obvious over the combination of Shamsuddin (U.S. Patent 5,162,202) in view of Lee et al.

Applicant respectfully traverses the foregoing rejection.

As argued above, Lee et al. cannot anticipate the invention. Lee et al. also cannot make the invention obvious in combination with the foregoing cited references. Lee et al. fails to provide any teaching or suggestion or the requisite motivation to make the claimed combination since spectrophotometrically measuring and

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electronically processing hue angle with or without chroma is neither suggested nor taught. To make a case for obviousness, the teachings in the art must be sufficient for an ordinary skilled artisan to make the proposed substitution, combination, or other modification. Lee et al. fails to adequately describe the meaning of the hue angle and chroma and as such no person skilled in the art would glean any teaching or suggestion to make the claimed combination. Lee et al.'s invention is based on a single number that reflects the total color difference (DE) as measured by L, a, b coordinate system, whereas the claimed invention is based on a measurement that is electrically processed for a hue angle over the entire visible spectrum with or without chroma. Lee et al.'s application to chromaticity and hue is incongruous and plainly, not focused on the technical aspects of color measurement as applied in the present application.

Therefore, contrary to the Examiner's proposed teaching or suggestion, Lee et al. fails to teach the particular aspect of reflectance spectrophotometry to determine chromaticity and hue to be applied to each of the Shamsuddin references to come up with the present invention successfully. Shamsuddin 4,857,457 and 5,162,202 describe methods of screening for large intestinal cancer using a known marker that is detected by treatment with galactose oxidase and Schiff's reagent. A positive result is indicated when color changes by using a color index reference chart (U.S. Patent 4,857,457, column 7, lines 5-8), by taking an optical absorbance reading at 405 nm (U.S. Patent 4,857,457, column 7, lines 46-47, and Patent 5,162,202, column 7, lines 57-59) or by a specific color formation, i.e., magenta color (U.S. Patent 5,162,202, column 7, lines 33-35). Both of these

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Shamsuddin patents are absolutely silent with regard to electronically processing hue angle with or without chroma.

Shamsuddin 5,348,860 is also directed to methods of cancer screening but for other bodily secretions. Similarly, this patent describes indicating a positive result through a single color change, e.g., magenta (column 9, lines 19-21), or by comparison to a color chart (e.g., column 9, lines 66-68). Shamsuddin 5,348,860 is absolutely silent with regard to electronically processing hue angle with or without chroma, therefore, cannot make the claimed invention obvious.

Consequently, any of the Shamsuddin references, either alone or in combination with Lee et al., fails to teach or suggest the claimed combination.

With respect to Krepinsky 5,416,025, this patent also screens for the early detection of colorectal cancer. However, this patent also indicates a positive result by a change in color, e.g., purple-magenta (column 6, lines 17-19). Krepinsky fails to teach or suggest electronically processing hue angle with or without chroma. Lee et al. fails to cure the deficiency found in Krepinsky since Lee et al. is also deficient in teaching or suggesting the claimed combination as described above. The requisite motivation to combine the references is not indicated.

Regarding Krepinsky 6,187,591, this is also a patent on a colorectal cancer screening test for rectal mucus in which a positive result is indicated by comparison to a color chart (column 7, lines 16-19). Krepinsky fails to provide any teaching or suggestion to apply accurate color measurements by electronically processing hue angle with or without chroma. Lee et al. is also deficient in such a teaching and would not cure the

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missing elements for a skilled artisan to come up with the invention successfully. Applicant respectfully requests reconsideration and withdrawal of the foregoing rejections.

Claim Rejection - 35 U.S.C §112

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, for being indefinite. The Examiner asserts that "a system" renders the claim indefinite.

Applicant respectfully traverses the foregoing rejection.

Applicant deems that the term "a system" is a widely used claim term for "a group of interacting, interrelated, or interdependent elements forming a complex whole" and is appropriate for the elements recited in the present claim 12.

(<http://dictionary.reference.com/search?q=system> [accessed December 11, 2003].) The elements recited in claim 12 are functionally related for the purpose of analyzing a liquid or semi-solid body secretion sample obtained from a human patient to diagnose for the presence or absence of abnormalities in said patient by determination of a defined color characteristic developed in the sample as described, at least, for example, on page 7, starting on the first full paragraph of the specification. For the Examiner's convenience, Applicant has provided a list of patents 1-50 (Attachment A) out of a total of 3,603 issued in the month of November 2003 that used the term "system" in the claims. Applicant asserts that the term is clear and definite and respectfully requests reconsideration of the foregoing rejection.

Furthermore, the Examiner queried the term "lightness". As known in the art, "lightness" is a color characteristic, or a

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degree of illumination, where an object may appear to reflect or transmit more or less of an incident light.

Title of the Invention

The Examiner objects to the title of the invention. Applicant considers that the title is clearly indicative of the scope of the claims. Applicant respectfully requests Examiner's suggestions on what he considers to be aptly descriptive.

Abstract and Priority Claim

Applicant has amended herein the specification to include the abstract filed in the corresponding International Application No. PCT/CA00/00918 thus satisfying the abstract objection.

Applicant has also amended the specification herein to include the appropriate priority claim thus satisfying the request of the Examiner.



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CONCLUSION

Based on the foregoing, entry of the amendments and remarks presented herein, reconsideration and withdrawal of all the rejections and allowance of application with all pending claims are respectfully requested.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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